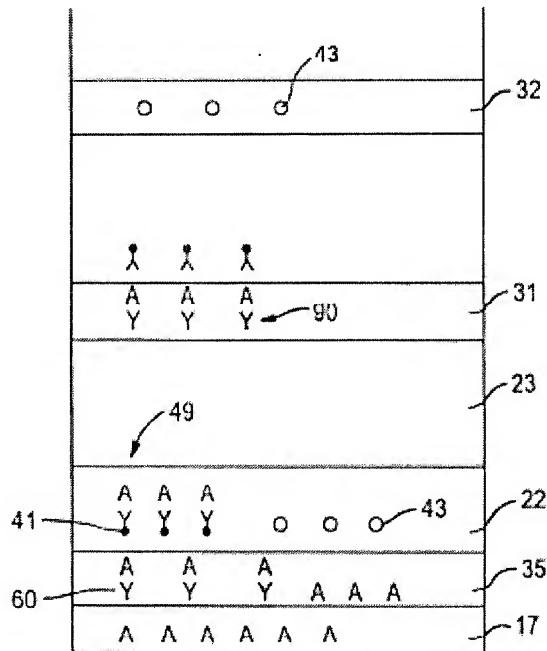


### REMARKS

Claims 2, 5-6, 12, and 37-47, including independent claim 37, are currently pending in the present application. To better understand the nature of the claimed invention, reference is made to an embodiment of the present application shown in Fig. 3, a portion of which is reproduced below.



In this embodiment, a test sample containing an analyte A is initially contacted with a sampling pad 17. At the sampling pad 17, a certain quantity of the analyte A binds to a first capture reagent 60 immobilized at the scavenging zone 35, such as an amount less than or equal to a predefined base quantity of analyte considered "normal" for the particular test sample. From the sampling pad 17, any analyte A in excess of the predefined base quantity travels to the conjugate pad 22, where it mixes with conjugated detection probes 41 and calibration probes 43. The excess analyte A binds with the conjugated detection probes 41 to form analyte/conjugated probe complexes 49. Because the conjugate pad 22 is positioned downstream from the scavenging zone

35, however, it is not necessary to supply detection probes 41 for binding to any of the analyte A that is already captured by the scavenging zone 35. In this manner, the overall amount of required probes is reduced, which provides substantial cost savings. At the detection zone 31, the complexes 49 are captured by a second capture reagent 90. If desired, the first capture reagent 60 at the scavenging zone 35 may be substantially identical to the second capture reagent 90. Thus, should any of the first capture reagent 60 somehow become free from the scavenging zone 35 and travel to the detection zone 31, it will not bind to the second capture reagent 90 and adversely impact the desired reduction in detection sensitivity. Further, the calibration probes 43 travel through the detection zone 31 to bind with a capture reagent (not shown) at the calibration zone 32. Once captured, the signal of the probes at the detection zone 31 and calibration zone 32 may be measured using any known method of detection, such as visually or with a reading device.

In the Office Action, independent claim 37 was rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 6,509,196 to Brooks, et al. in view of U.S. Patent No. 6,258,548 to Buck. Brooks, et al. describes a membrane strip that includes an application point, a contact region, and a detection zone. The contact region includes test particles and internal control particles. The test particles are coated with a binding agent for the analyte, such as an antibody. The internal control particles are also coated with a binding agent. However, the binding agent of the control particles is not specific for the analyte, such as an antibody that binds to an antigen that is uninvolved in the assay. In Example 1, for instance, the test particles are coated with a mouse monoclonal antibody that is specific for a myoglobin analyte. On the other hand, the

internal control particles are coated with mouse monoclonal antibody MOPC31-c, which has an unknown specificity for myoglobin. According to Brooks, et al., the purpose of using such internal control particles, which are not specific for the analyte, is to determine the amount of “non-specific binding” that occurs during the assay. As correctly noted by the Examiner, however, Brooks, et al. fails to disclose numerous limitations of independent claim 37. For example, Brooks, et al. completely fails to disclose the claimed “scavenging zone.”

The Office Action nevertheless attempted to cure the deficiencies noted above by combining Brooks, et al. with Buck. Applicants respectfully submit, however, that this combination is misplaced due to the vastly different nature of the systems of these references. The analyte modulating zone of Buck, for instance, does not take into account the non-specific binding that Brooks et al. is concerned with and, therefore, would impact the operation of Brooks et al. and the quantitative calculation of the analyte.

In any event, one of ordinary skill in the art would not have found it obvious to combine the references in the manner proposed in the Office Action as it would completely vitiate the purpose of Brooks, et al. Namely, Brooks, et al. relies on internal control particles that can *flow through the strip* to help account for any non-specific binding that may occur during performance of the assay. The present claims operate in exactly the opposite manner in that the scavenging zone contains a non-diffusively immobilized capture reagent that is able to “capture” a certain quantity of the analyte. If the capture reagent in the scavenging zone flowed through the membrane in the same manner as the particles of Brooks, et al., the entire purpose of the scavenging zone

would be eliminated as the analyte within the scavenging zone could then become bound within the detection zone.

Thus, for at least the reasons indicated above, Applicants respectfully submit that the presently claims patentably define over the cited references, taken singularly or in any proper combination. It is believed that the present application is in complete condition for allowance and favorable action, therefore, is respectfully requested. Examiner DiRamio is invited and encouraged to telephone the undersigned, however, should any issues remain after consideration of this Response.

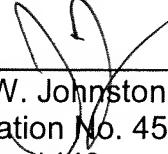
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Respectfully requested,

DORITY & MANNING, P.A.

9/25/08

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